



**DEPARTMENT OF DEFENSE**

**BILLING CODE 5001-06**

**Office of the Secretary**

**32 CFR Part 199**

**DOD-2009-HA-0038**

**RIN 0720-AB50**

**TRICARE: Smoking Cessation Program**

**AGENCY:** Office of the Secretary, Department of Defense.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements Section 713 of the Duncan Hunter National Defense Authorization Act (NDAA) for Fiscal Year 2009. Section 713 states the Secretary shall establish a smoking cessation program under the TRICARE program. The smoking cessation program under TRICARE shall, at a minimum, include the following: the availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with the limitation on the availability of such pharmaceuticals to the mail-order pharmacy program under the TRICARE program; smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; access to print and Internet web-based tobacco cessation material. Per the statute, Medicare-eligible beneficiaries are excluded from the TRICARE smoking cessation program.

**EFFECTIVE DATE:** This final rule is effective [INSERT 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Ms. Ginnean Quisenberry,  
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## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### **A. Purpose of the Final Rule.**

The purpose of this final rule is to implement the provisions of the Duncan Hunter NDAA for FY 2009 (Pub. L. 110-417) that establishes a smoking cessation program under the TRICARE program. Establishment of the TRICARE smoking cessation program attempts to reduce the number of TRICARE beneficiaries who are nicotine dependent, thereby improving the health of the TRICARE beneficiary population and reducing Department of Defense costs, in particular those related to the adverse effects of smoking. The legal authority for the Final Rule is Section 713 of the Duncan Hunter NDAA FY09 (Pub. L. 110-417).

#### **B. Summary of the Major Provisions of the Final Rule**

Section 713 of the Duncan Hunter NDAA for FY 2009 stipulates the following key features for inclusion in the TRICARE smoking cessation program:

1. *The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program if appropriate.*

Smoking cessation medications will be covered by TRICARE through the Mail Order Pharmacy program, as well as at Military Treatment Facilities at no cost,

including no co-pay. The type of smoking cessation medications available, which may include over-the-counter medications, will be determined by the TRICARE Pharmacy and Therapeutics Committee based on clinical and cost effectiveness considerations.

2. *Counseling*

In person smoking cessation counseling from a TRICARE authorized provider as detailed in the TRICARE Policy Manual for is a covered TRICARE benefit for those beneficiaries that are not eligible for Medicare.

3. *Access to a toll-free quit line that is available 24 hours a day, 7 days a week.*

Beneficiaries will have access to a toll-free smoking cessation quit line that will be available 24 hours a day, 7 days a week.

4. *Access to print and Internet web-based tobacco cessation material.*

TRICARE will provide access to both print and web-based tobacco cessation materials for any beneficiary who is interested in quitting using tobacco products.

5. *Chain of command involvement by officers in the chain of command of participants in the program who are on active duty.*

All of those in the chain of command are expected to provide their support to the program and to any member who wishes to quit smoking. There is no intent for any reporting requirements to the chain of command related to any member's participation.

### C. Costs and Benefits of this Regulatory Action.

The cost for these changes is estimated to be 24 million dollars for a one year period. The benefits are that TRICARE will be in compliance with its statutory provisions and health of beneficiaries who quit smoking will be improved.

## II. Background

The Duncan Hunter NDAA for FY 2009 (Pub. L. 110-417) provides authority for establishment of a smoking cessation program under the TRICARE program. Prior to enactment of Section 713 of the Duncan Hunter NDAA FY09 (Pub. L. 110-417), all supplies and services related to “stop smoking” programs were excluded from TRICARE coverage per the regulation, 32 CFR 199.4(g)(65).

Smoking is the number one cause of *preventable* illness and disease in the United States and yet, the prevalence of smoking among TRICARE beneficiaries exceeds that of the general population. According to the Centers for Disease Control and Prevention (CDC), adverse health effects from smoking account for an estimated 443,000 deaths in the United States each year.

Smoking causes respiratory diseases such as emphysema, bronchitis, and chronic airway obstruction. It also causes several types of cancers including, but not limited to, esophageal, oral cavity, uterine, and lung cancer. In fact, the CDC estimates that 90 percent of lung cancer deaths in men and 80 percent in women are caused by smoking.

Smoking also puts individuals at increased risk for several other types of diseases and adverse health outcomes such as coronary artery disease, chronic obstructive lung diseases, peripheral vascular disease, heart attack, and stroke. In addition, it increases the

risk of infertility, preterm delivery, stillbirth, low birth weight, and sudden infant death syndrome.

Smoking and its related adverse effects pose a significant challenge for many TRICARE beneficiaries. Establishment of the TRICARE smoking cessation program attempts to reduce the number of TRICARE beneficiaries who are nicotine dependent, thereby improving the health of the TRICARE beneficiary population and reducing Department of Defense costs, in particular those related to the adverse effects of smoking. For further information on TRICARE and the benefits provided under the TRICARE program, please visit [www.tricare.mil](http://www.tricare.mil).

### **III. Section 713 of the Duncan Hunter NDAA for FY 2009**

This final rule implements Section 713 of the Duncan Hunter NDAA for FY 2009. Section 713 stipulates the following key features for inclusion in the TRICARE smoking cessation program:

(1) The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program if appropriate.

(2) Counseling.

(3) Access to a toll-free quit line that is available 24 hours a day, 7 days a week.

(4) Access to print and Internet web-based tobacco cessation material.

(5) Chain of command involvement by officers in the chain of command of participants in the program who are on active duty.

Additionally, Section 713 of NDAA FY 2009 stated the TRICARE smoking cessation program shall not be made available to Medicare-eligible beneficiaries. The statutory language further stated that refunds of copayments paid by Medicare-eligible beneficiaries are available during fiscal year 2009, subject to the specific availability of appropriations for this purpose. However, this authority was not extended beyond FY 2009; consequently, no action is required by TRICARE regarding this provision.

#### **IV. Final Rule.**

This final rule establishes a smoking cessation program under the TRICARE program. The TRICARE smoking cessation program will be available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In general, the TRICARE smoking cessation program will not be available to TRICARE beneficiaries who reside overseas except that under authority of 32 CFR 199.17, active duty service members and active duty dependents residing overseas including the U.S. territories of Guam, Puerto Rico, and the Virgin Islands who are enrolled in TRICARE Prime at a military treatment facility may have access to those services that the ASD(HA) has determined may be reasonably provided overseas.

It is the intent of the Department to provide access to smoking cessation pharmaceuticals and web based smoking cessation materials overseas where feasible. However, beneficiaries residing in certain areas overseas may not have easy access to the

mail services, equipment or technology needed to receive these smoking cessation benefits and in those areas there is no requirement to make them available. For example, there is no intent by the Department to make the web based services available in areas where there are no web based carriers to provide such a service. Additionally, the laws and our treaties with various countries restrict the mailing of pharmaceuticals into the country. If such laws or treaties do not allow the delivery of the pharmaceuticals through the TRICARE Mail Order Pharmacy (TMOP), it is not the intent of the Secretary to provide the pharmaceutical benefit in those areas through this mechanism.

At this time, it is not the intent of the Department to provide access to the toll free quit line overseas due to the technological barriers and cost involved in providing this service. In addition, it is not the intent of the Department at this time to make face-to-face smoking cessation counseling available overseas through the local economy. However, in accordance with 32 CFR 199.17 should the ASD(HA) determine that it is technologically, economically, or otherwise feasible to provide additional benefits or it becomes impractical to continue the benefits and services overseas, the ASD(HA) may use this authority to add or modify any benefit or service. Notice of the use of this authority shall be published in the Federal Register.

There will be no requirement for an eligible beneficiary to be diagnosed with a smoking related illness in order to access benefits under the TRICARE smoking cessation program. Benefits under this program will include, at no cost to the beneficiary, pharmaceuticals used for smoking cessation available through the TRICARE mail-order pharmacy program and at Military Treatment Facilities. The program will include

smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; and access to printed and Internet web-based tobacco cessation material. Like other pharmaceuticals, smoking cessation pharmaceuticals may also be available at no cost to the beneficiary at an MTF; however, smoking cessation pharmaceuticals are not a covered benefit under the TRICARE Retail Pharmacy program.

## **V. Public Comments**

The proposed rule was published in the Federal Register (76 FR 58199) dated September 20, 2011, for a 60-day public comment period. We received sixteen comments from different respondents on the proposed rule.

All but one of the public comments was positive and supported the provisions of the proposed rule. Fifteen of the respondents approved of the new coverage of smoking cessation medications with no copay, however there were two comments questioning the limitation of availability to the Mail Order Pharmacy Program. There was concern that TRICARE had not explained the reasoning for this decision and some were concerned that this limitation would be a barrier to those seeking treatment. We appreciate the comments and acknowledge the concern. However, we do not believe that limiting availability of smoking cessation pharmaceuticals to the mail order pharmacy will be a barrier to seeking care by the majority of beneficiaries. Mail order is a more cost effective venue than retail pharmacy and this limitation is a way of controlling the cost of providing these pharmaceuticals at no cost to the beneficiary. We believe that providing these pharmaceuticals at no cost has a greater influence on a beneficiary's decision to seek care than the fact that the care is limited to a specific venue. We believe this to be a prudent, fair, and reasonable approach to providing the pharmaceutical component of the benefit.



Additionally, one respondent, representing the National Community Pharmacists Association felt that since some retail pharmacists provide smoking cessation counseling, it would be more convenient for beneficiaries to be able to get their medications at the retail pharmacy where they might possibly be going for smoking cessation counseling, so that both activities could occur in one location. We appreciate the respondent's comment and the suggestion that would seemingly offer greater convenience to TRICARE beneficiaries; however, consistent with Center for Medicare and Medicaid Services (CMS), pharmacists are not recognized as authorized TRICARE independent providers. Although TRICARE currently recognizes pharmacies as providers for purposes of the pharmacy benefits program under 32 CFR 199.21, which includes providing immunizations to our beneficiaries, the individual pharmacist is not recognized as an independent provider. Therefore, pharmacist counseling services are not currently a covered benefit under TRICARE and pharmacists cannot be reimbursed for this service. Therefore, beneficiaries who obtain smoking cessation products in a retail pharmacy may not receive counseling from the pharmacist as a covered benefit. In addition, as mentioned above, providing these products in the retail venue would significantly increase the cost of this program. The respondents were also concerned that if medications for smoking cessation are mailed to a patient's home, they will not have the opportunity to ask questions of a pharmacist before taking them. Unlike the majority of retail pharmacies, the mail order pharmacy program provides access to pharmacists 24/7 via a toll free number. Consistent with most pharmacy services, the mail order program provides complete written information including instructions for use, side effects, adverse effects, doses, warnings, and telephone numbers for questions.

Five respondents expressed concern that these new benefits were only available CONUS and not OCONUS. One respondent suggested a change to the language that deals with OCONUS availability. The commentor would prefer that it say that TRICARE is required to make the smoking cessation program available overseas unless the ASD (HA) determines it is not possible to provide the program in specific overseas locations or situations, instead of stating that the benefits are not available overseas unless the Assistant Secretary of Defense for Health Affairs [ASD(HA)] determines they can be reasonably provided. We appreciate the respondent's comments and acknowledge the respondent's suggestion, however during the implementation of this benefit the ability to provide the benefit overseas was extensively explored. The Department found significant barriers and elected not to implement at this time. The language gives the Assistant Secretary the ability to expand the benefit as technology and other innovations make the delivery of these benefits feasible. Additionally the current federal regulations relating to the implementation of TRICARE overseas states that the program is not implemented overseas without affirmative action by the Department, thus the language used is consistent with our current regulatory framework.

One person commented that the smoking cessation program should include provisions to assist with tobacco cessation as well. We appreciate the comment; however, the language in section 713 of the NDAA 2009 limits us to providing a smoking cessation program with one exception. That exception allows the Department to provide printed and Internet web-based tobacco cessation materials.

One respondent was concerned that the language in the summary statement that says that there is a "limitation on the availability of such pharmaceuticals to the mail-order pharmacy" will cause the beneficiaries to believe that they cannot get these medications at the MTF pharmacies.

We appreciate the respondent's comment and concern, and would like to assure the respondent that this was unintentional. To correct this and assure clarity, the language in Section III, the Summary, concerning the availability of smoking cessation pharmaceuticals has been revised to include a reference to the availability of pharmaceuticals at the MTFs. The language in the regulation itself reflects the correct availability of these pharmaceutical agents.

The statement in the proposed rule that says, "the Secretary of Defense shall provide for involvement by officers in the chain of command of participants in the program who are on active duty" caused concern for one responder. This commenter took this statement to mean that those active duty members who took advantage of the program would have to report on their progress to their supervisor, which they felt would be very intimidating for those trying to quit, especially if they were having difficulties. We appreciate the comment, and want to clarify that the intent is not to have supervising officers be directly involved in individual active duty service members quit attempts, but to have them provide their support to the program. That is, it is the intent of the Department for all parts of the chain of command to support any member who wishes to quit smoking. There is no intent for any reporting requirements by a member to his or her command or for any member within the chain of command to report to their superiors relating to any member's participation in a smoking cessation program.

There were several comments related to the number of quit attempts available to participants in the program. One respondent did not think that a beneficiary should get more than three attempts total. The commenter was opposed to having three possible attempts per year and felt it would be a waste of TRICARE resources to continue to pay for additional attempts for someone who was not successful within a year of trying. We acknowledge the respondent's comments and appreciate the concerns. TRICARE is dedicated to the appropriate and judicious

use of taxpayers' money and the decision to allow more than three quit attempts in total was the result of extensive research concerning smoking cessation. This research revealed that, on average, it takes smokers seven attempts to quit. Allowing more than three total attempts will give TRICARE beneficiaries who want to quit smoking the best opportunity to do so. This will result in a healthier beneficiary population; and as this population becomes healthier and more individuals choose to quit, TRICARE health care costs associated with treating diseases that are either caused by or exacerbated by smoking will be reduced.

Another respondent had the opposite view, believing that since "tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit", patients should not be limited in their attempts and should have access to tobacco cessation services throughout the year. We acknowledge and respect this respondent's point of view; however, believe it would be fiscally irresponsible not to impose a limit on quit attempts. Furthermore, while our research revealed that the average person requires multiple attempts at quitting before they are successful, our research did not support a conclusion that allowing unlimited quit attempts results in improved success rates.

This respondent also requested that the DoD Pharmacy and Therapeutics Committee, when deciding which specific smoking cessation medications TRICARE will cover, will choose to include all FDA-approved tobacco cessation medications. We appreciate this respondent's comment and suggestion. The Pharmacy and Therapeutics Committee has a mandate to review and recommend drugs based on their clinical and cost effectiveness. After this formal process, these recommendations will then go to the TMA Director, who will make the final decision. At this point, we do not know which of the smoking cessation medications will, or will not be on the formulary.

Another comment requested that TRICARE providers be made aware of the available cessation benefits and be trained in smoking cessation counseling. We appreciate the respondent's comments and suggestions and want to assure this respondent that once the final rule is published and this becomes a TRICARE benefit, information concerning it will be well publicized. This publicity will include information for TRICARE providers and our beneficiaries. Information concerning this new benefit will also be available on the TRICARE website ([www.TRICARE.mil](http://www.TRICARE.mil)), which is accessible to beneficiaries, providers and the general public. In addition, the Managed Care Support Contractors are required to disseminate information to providers affected by implementation of new TRICARE benefits.

Another comment recommended an expansion of the TRICARE smoking cessation program to include a reduction of tobacco advertising in military literature and increasing the cost of tobacco products on military bases. We appreciate this respondent's comment and suggestions; however, the authority to take the actions suggested is beyond the scope of the requirements of the law that TRICARE was tasked to implement.

Unrelated to the Proposed Rule on Smoking Cessation, one comment was received from a retiree who was upset that he might be forced to pay more for TRICARE Prime as a part of DoD cutbacks. We appreciate this respondent's comments; however, we cannot address these here as they are outside the scope of the law that implements the TRICARE smoking cessation benefits.

## **VI. Regulatory Procedures.**

**Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"**

Section 801 of title 5, United States Code, and Executive Orders 12866 and 13563 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. This final rule is not a significant regulatory action.

**Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601)**

Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule will not have a significant impact on a substantial number of small entities. Therefore, this final rule is not subject to the requirements of the RFA.

**Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)**

This rule does not contain a “collection of information” requirement, and will not impose additional information collection requirements on the public under Pub. L. 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35).

**Public Law 104-4, Section 202, “Unfunded Mandates Reform Act”**

Section 202 of Pub. L. 104-4, “Unfunded Mandates Reform Act,” requires that an analysis be performed to determine whether any federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. This final rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or

by the private sector, of \$100 million or more in any one year, and thus this final rule is not subject to this requirement.

### **Executive Order 13132, “Federalism”**

Executive Order 13132, “Federalism,” requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule does not have federalism implications, as set forth in Executive Order 13132.

### **List of Subjects in 32 CFR Part 199**

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

#### **PART 199--[AMENDED]**

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. Chapter 55.

2. Section 199.4 is amended by:

- a. Revising paragraph (d)(3)(vi) introductory text.
- b. Adding new paragraph (d)(3)(vi)(C).
- c. Adding new paragraph (e)(30).
- d. Revising paragraph (g)(39).
- e. Removing and reserving paragraph (g)(65).

The revisions and additions read as follows:

**§ 199.4 Basic program benefits.**

\* \* \* \* \*

(d) \* \* \*

(3) \* \* \*

(vi) Drugs and medicines. Drugs and medicines that by United States law require a prescription are also referred to as “legend drugs.” Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider’s license and ordered or prescribed in connection with an otherwise covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

\* \* \* \* \*

(C) Over-the-counter (OTC) drugs (drugs that by United States law do not require a prescription), in general, are not covered. However, insulin is covered for a known diabetic even in states that do not require a prescription for its purchase. In addition, OTC drugs used for smoking cessation are covered when all requirements under the TRICARE smoking cessation program are met as provided in paragraph (e)(30) of this section.

\* \* \* \* \*

(e) \* \* \*

(30) Smoking cessation program. The TRICARE smoking cessation program is a behavioral modification program to assist eligible beneficiaries who desire to quit



smoking. The program consists of a pharmaceutical benefit; smoking cessation counseling; access to a toll-free quit line for non-medical assistance; and, access to print and internet web-based tobacco cessation materials.

(i) Availability. The TRICARE smoking cessation program is available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In addition, pursuant to § 199.17, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE smoking cessation program may be implemented in whole or in part in areas outside the 50 states and the District of Columbia for active duty members and their dependents who are enrolled in TRICARE Prime (overseas Prime beneficiaries). In such cases, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the TRICARE smoking cessation program rules and procedures as may be appropriate to the overseas area involved. Notice of the use of this authority, not otherwise mentioned in this paragraph (e)(30), shall be published in the Federal Register.

(ii) Benefits. There is no requirement for an eligible beneficiary to be diagnosed with a smoking related illness to access benefits under this program. The specific benefits available under the TRICARE smoking cessation program are:

(A) Pharmaceutical agents. Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in § 199.21. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the

TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary.

Smoking cessation pharmaceuticals through the TRICARE program will not be available at any retail pharmacies. A prescription from a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

(B) Face-to-face smoking cessation counseling. Both individual and group smoking cessation counseling are covered. The number and mix of face-to-face counseling sessions covered under this program shall be determined by the Director, TMA; however, shall not exceed the limits established in paragraph (e)(30)(iii) of this section. A TRICARE-authorized provider listed in § 199.6 must render all counseling sessions.

(C) Toll-free quit line. Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should

the ASD(HA) exercise his authority to do so and provide appropriate notice in the Federal Register.

(D) Web-based resources. Downloadable educational materials on the effects of tobacco use will be available through the internet or other electronic media. This service may be made available to overseas Prime beneficiaries in all locations where web based resources are available. There shall be no requirement to create web based resources in any geographic area in order to make this service available.

(iii) Limitations of smoking cessation program. Eligible beneficiaries are entitled to two quit attempts per year (consecutive 12 month period). A third quit attempt may be covered per year with physician justification and pre-authorization. A quit attempt is defined as up to eighteen face-to-face counseling sessions over a 120 consecutive day period and/or 120 days of pharmacologic intervention for the purpose of smoking cessation. Counseling and pharmacological treatment periods that overlap by at least 60-days are considered a single quit attempt.

\* \* \* \* \*

(g) \* \* \*

(39) Counseling. Educational, vocational, and nutritional counseling and counseling for socioeconomic purposes, stress management, and/or lifestyle modification purposes, except that the following are not excluded:

(i) Services provided by a certified marriage and family therapist, pastoral or mental health counselor in the treatment of a mental disorder as specifically provided in paragraph (c)(3)(ix) of this section and in § 199.6.

(ii) Diabetes self-management training (DSMT) as specifically provided in paragraph (d)(3)(ix) of this section.

(iii) Smoking cessation counseling and education as specifically provided in paragraph (e)(30) of this section.

(iv) Services provided by alcoholism rehabilitation counselors only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

\* \* \* \* \*

(65) [Reserved]

\* \* \* \* \*

3. Section 199.21 is amended by:

- a. Revising paragraph (a)(2);
- b. Revising paragraph (h)(2)(i);
- c. Adding a new paragraph (h)(2)(iii); and
- d. Adding a new (i)(2)(v)(D).

The additions and revisions read as follows:

**§ 199.21 Pharmacy benefits program.**

(a) \* \* \*

(2) Pharmacy benefits program. (i) Applicability. The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Geographically, except as specifically provided in paragraph (a)(2)(ii) of this section, this program is applicable to all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)), the TRICARE pharmacy benefits program may be implemented in areas outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the ASD (HA) may also authorize modifications to the pharmacy benefits program rules and procedures as may be appropriate to the area involved.

(ii) Applicability exception. The pharmaceutical benefit under the TRICARE smoking cessation program under § 199.4(e)(30) is available to TRICARE beneficiaries who are not entitled to Medicare benefits authorized under Title XVIII of the Social Security Act. Except as noted in § 199.4(e)(30), the smoking cessation program, including the pharmaceutical benefit, is not applicable or available to beneficiaries who reside overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, except that under the authority of § 199.17 active duty service members and active duty dependents enrolled in TRICARE Prime residing overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, shall have access to smoking cessation pharmaceuticals through either an MTF or the TMOP program where available.

\* \* \* \* \*

(h) \* \* \*

(2) Availability of formulary pharmaceutical agents. (i) General. Subject to paragraphs (h)(2)(ii) and (h)(2)(iii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all points of service identified in paragraph (h)(1) of this section.

\* \* \* \* \*

(iii) Pharmaceutical agents prescribed for smoking cessation are not available for coverage when obtained through a retail pharmacy. This includes network and non-network retail pharmacies.

\* \* \* \* \*

(i) \* \* \*

(2) \* \* \*

(v) \* \* \*

(D) \$0.00 co-payment for smoking cessation pharmaceutical agents covered under the smoking cessation program.

\* \* \* \* \*

DATED: February 1, 2013.

Patricia L. Toppings

OSD Federal Register Liaison Officer

Department of Defense

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